

## BEST AVAILABLE COPY

### REMARKS

A copy of the requested terminal disclaimer as previously filed is enclosed herewith.

Copies are enclosed herewith of the references listed in applicant's Information Disclosure Statement that ostensibly are not available in the Patent Office file of the subject application.

The specification has been objected to for inadequately updated citations of the related applications. By recent submission of the amendment labeled "Preliminary Amendment" filed on or about August 25, 2004, the paragraph on page 1 entitled "Related Cases" was updated to cite a recently-issued patent in the continuing data. The specification is amended herewith at page 1 to correct the status of applications as no longer co-pending where patents have issued thereon. It is therefore respectfully submitted that these revisions obviate the bases for objection to the specification.

Claim 5 has been objected to as including a grammatically awkward term. Applicant has amended the claim in consideration of the Examiner's comments and suggestions to obviate this basis for objection. As amended, claim 5 is now submitted to define the invention with sufficient particularity and distinctiveness to be patentable to applicant.

Claims 7-9 have been rejected under the judicially-created doctrine of obviousness-type double patenting over claims 2-6 of U.S. Patent No. 6,401,721. Also, claims 1-5 have been rejected for obviousness-type double patenting over claims 1 and 3 of U.S. Patent No. 5,749,375. And, claims 11, 12 and 14 have been rejected for obviousness-type double patenting over claims 11, 12 and 15 of U.S. Patent No. 5,571,167. The '721 and '375 patents all variously derive priority from U.S. Patent No. 5,571,167.

The assignee of the entire interests in the subject application and in the Patents nos. 6,401,721; 5,749,375; and 5,571,167 is filing a Terminal Disclaimer herewith to obviate such bases for rejections of claims. It is therefore respectfully submitted that claims 1-5, 7-9 and 11, 12, 14 are now patentable to applicant.

Claims 1, 2, 4, 7 and 10 are rejected under 35 USC §102(e) as being anticipated by Wilk '861. This rejection is respectfully traversed with respect to these claims as amended herein.

The Examiner's allusion to claims 6 and 8, though not listed as being rejected under 35 USC §102(e) over Wilk '861, are considered by the undersigned to be included in this rejection and are patentably distinguishable for reasons as set forth in the following Remarks.

Specifically, these claims variously recite the method including "creating an arteriotomy in the blood vessel by extravascular manipulation at a selected

location”, or “extravascularly creating an arteriotomy in the blood vessel at a selected location;”, or “positioning an end of an instrument having a lumen therethrough extravascularly near a selected location along the aorta”, or “extravascularly positioning an end of an instrument having a lumen therethrough near a selected location along the blood vessel”.

Additionally, the dependent claims are further limited by recitations of the blood vessel involved, or the positioning of the conduit or graft relative to the blood vessel.

These aspects of the claimed invention are not disclosed by Wilk ‘861 which relies upon intravascular placement of a stent that connects a ventricle and coronary artery using tools inserted within the vessel and that penetrate past the occlusion which is to be bypassed with supplemented blood flow. There is no disclosure or suggestion in this reference of subject matter as claimed by Applicant, and it is therefore respectfully submitted that claims 1, 2, 4, 6-8 and 10 as amended herein are not anticipated by, but instead are patentably distinguishable over Wilk ‘861.

Claims 1-5, and 7 have been rejected under 35 USC §103(a) as being unpatentable over Brewster in view of Ablaza ‘909. This rejection is respectfully traversed.

These claims as now amended specifically recite “creating an arteriotomy in the blood vessel by extravascular manipulation at a selected location”, or “creating an arteriotomy in the aorta at a selected location via an initial entry at a location relative to a femoral artery below the inguinal ligament”, or “positioning an end of an instrument having a lumen therethrough near a selected location along the aorta”. In addition, the dependent claims are further limited to the aorta and a selected location thereon.

These aspects of the claimed invention are not disclosed or even suggested by the cited references considered either alone or in the combination proposed by the Examiner. Although Brewster discloses side-to-end anastomosis, neither this reference nor Ablaza '909 alone or combined with Brewster is understood to disclose or suggest a grafting procedure as now claimed by Applicant. And, contrary to the Examiner's analyses of Ablaza '909, this reference is not understood to perform a grafting procedure for establishing blood flow outside the vessel, nor perform such procedure at a selected location covered by substantially intact portion of the epidermis, as claimed. Instead, these combined references at best disclose a grafting procedure on the tissue structure of a vessel that is not epidermis (or, inner layer of skin). And, the Examiner's comments correlating “an incision where the connection point (in vessel tissue that is not epidermis) is under completely intact skin,” overlooks substantial anatomical distinctions and different

locations on the body. Also, these references disclose substantially exposed surgical sites, with no associated instruction or motivation found for combining such references, as the Examiner proposes, to suggest using an instrument with a lumen therethrough at an exposed surgical site. It is therefore respectfully submitted that claims 1-5 and 7 are now patentably distinguishable over the cited art.

Claims 6 and 8 have been rejected under 35 USC §103(a) as being unpatentable over Wilk '861 in view of Loiterman '165. This rejection is respectfully traversed with respect to those claims as amended herein.

These claims now specifically recite “extravascularly creating an arteriotomy in the blood vessel at a selected location”, and the dependent claim is further restricted by specific recitations of “positioning an end of an instrument having a lumen therethrough near a selected location along the aorta”, and of the positioning of an endoscope.

These aspects of the claimed invention are not disclosed or even suggested by the cited references considered either alone or in the combination proposed by the Examiner.

Specifically, Wilk '861 and Loiterman '165 rely upon intravascular procedures that provide no foundation for the Examiner's extrapolation to features of the invention claimed by Applicant. To the contrary, the deficient disclosures of

these references, considered either alone or in combination, fail to establish even a *prima facie* basis including the specific steps and functions as claimed from which a proper determination of obviousness can be made. It is therefore respectfully submitted that amended claims 6 and 8 are now patentably distinguishable over the cited art.

Claim 9 has been rejected under 35 USC §103(a) as being unpatentable over Brewster and Ablaza '909, as applied to claims 1-5 and 7 above, further in view of Loiterman '165. This rejection is respectfully traversed.

This claim specifically recites “positioning an end of an endoscope having a lumen therethrough near a selected location along the aorta” and “the endoscope is positioned via an initial entry at a location relative to a femoral artery below the inguinal ligament”.

These specific recitations define a procedure that finds no semblance of equivalence or similarity in the cited references considered either alone or in the combination proposed by the Examiner. As the Examiner correctly notes, the disclosure of Brewster is deficient of any disclosure of the use of an endoscope as claimed. And, Ablaza '909 merely discloses installing an intravascular stent. These references are understood to disclose substantially exposed surgical sites for which an endoscope would be unnecessary, certainly from the entry location as claimed. Thus, merely adding the additional intravascular steerable device of

Loiterman '165 fails to establish or even suggest a procedure as claimed by Applicant. The deficient disclosures of these cited references thus fail to establish even a *prima facie* basis from which a proper determination of obviousness can be made. It is therefore respectfully submitted that claim 9 as amended is now patentably distinguishable over the cited art.

Claims 11-13 have been rejected under 35 USC §103(a) as being unpatentable over Brewster and Ablaza '909 as applied to claims 1-5 and 7 above, further in view of Barone et al. '443. This rejection is respectfully traversed.

These claims specifically recite "placing the graft between the first aperture in the first artery and the second aperture in the second artery". These aspects of the claimed invention are not disclosed or even suggested in the cited references.

The deficient disclosures of Brewster and Ablaza '909 are discussed in the above Remarks, and Barone '443 merely discloses intravascular positioning and installation of a bifurcated stent. There is thus no hint or suggestion in these references of performing the surgical procedure as claimed by Applicant. It is therefore respectfully submitted that these claims are patentably distinguishable over the cited art.

Reconsideration and allowance of all pending claims are solicited.

Respectfully submitted,  
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Dated: 10/1/04

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ATTACHMENTS:

Copy of previous Terminal Disclaimer  
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